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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,651	07/12/2001	Hiroyuki Nakane	77670/495	2816
7550 11/09/2009 King L. Wong, Esq Kenyon & Kenyon LLP			EXAMINER	
			STEADMAN, DAVID J	
1500 K St. N.V Suite 700	V.		ART UNIT	PAPER NUMBER
Washington, DC 20005			1656	
			MAIL DATE	DELIVERY MODE
			11/09/2009	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 09/902.651 NAKANE ET AL. Office Action Summary Examiner Art Unit David J. Steadman 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 29 September 2009 and 02 October 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.3.4.6.7.11-16 and 49-54 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1.3.6.11-15 and 49-54 is/are allowed. 6) Claim(s) 7 and 16 is/are rejected. 7) Claim(s) 4 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) □ Some \* c) □ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 08/898,560. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other:

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#### DETAILED ACTION

#### Status of the Application

[1] A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/2/09 has been entered.

- [2] Claims 1, 3-4, 6-7, 11-16, and 49-54 are pending in the application.
- [3] Receipt of a substitute reissue declaration under 37 CFR 1.175, filed on 9/29/09, is acknowledged.
- [4] Receipt of a statement under 37 CFR 3.73(b), filed on 9/29/09, is acknowledged.
- [5] Receipt of a supplemental reissue declaration under 37 CFR 1.175, filed on 9/29/09, is acknowledged.
- [6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

#### Informalities

[7] The objection to the application under 37 CFR 1.172(a) is <u>withdrawn</u> in view of the statement under 37 CFR 3.73(b), filed on 9/29/09. Application/Control Number: 09/902,651

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[8] The objection to the reissue oath/declaration filed with this application as being defective (see 37 CFR 1.175 and MPEP § 1414) is <u>withdrawn</u> in view of the substitute reissue declaration under 37 CFR 1.175 and the supplemental reissue declaration under 37 CFR 1.175 to correct errors statement, both filed on 9/29/09.

#### Claim Objection

[9] Claim 4 is newly objected to in the recitation of "mutant prenyl diphosphate synthase is a homodimer" and in order to improve claim form, it is suggested that the noted phrase be amended to recite, *e.g.*, "mutant prenyl diphosphate synthase forms a homodimer".

### Claim Rejections – Defective Oath/Declaration

[10] The rejection of claims 1, 3-4, 6-7, 11-16, and 49-54 as being based on a defective Oath/Declaration is <u>withdrawn</u> in view of the substitute reissue declaration under 37 CFR 1.175 and the supplemental reissue declaration under 37 CFR 1.175 to correct errors statement, both filed on 9/29/09.

### Claim Rejections - 35 USC § 112, Second Paragraph

[11] Claim 16 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 is indefinite as depending from canceled claim 2. It is suggested that applicant clarify the meaning of the claim by replacing the phrase, "any one of claims 1 to 4, 6 and 7" with, e.g., "any one of claims 1, 3, 4, 6, and 7".

### Claim Rejections - 35 USC § 112, First Paragraph

[12] Claims 7 and 16 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163.II.A.3.(b) states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description". According to MPEP § 2163.I.B, "While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure" and "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117".

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Claim 7 (claim 16 dependent therefrom) recites, "the mutant prenyl diphosphate synthase is more thermostable than the wild-type geranylgeranyl diphosphate synthase of *Sulfolobus acidocaldarius*". According to the remarks filed on 3/6/09 at p. 5, this limitation is supported by the specification at Example 5 and Figure 2.

However, this disclosure does not appear to provide adequate descriptive support for the noted limitation at least for the reasons that follow. According to Example 5, "The mutant prenyl diphosphate synthase has exhibited a thermo stability which is equal to that of the native geranylgeranyl diphosphate synthase", where the "native geranylgeranyl diphosphate synthase" is wild-type *Sulfolobus acidocaldarius* geranylgeranyl diphosphate synthase. Thus, while this disclosure provides descriptive support for the mutant prenyl diphosphate synthase having thermostability equal to wild-type *Sulfolobus acidocaldarius* geranylgeranyl diphosphate synthase, it does not support the mutant prenyl diphosphate synthase having greater thermostability.

The results of Figure 2 indicate that while the mutant enzymes have a greater relative activity at 70 or 80 degrees Celsius, they do not have greater relative activity at 60 degrees Celsius. Thus, while this disclosure provides descriptive support for the mutant prenyl diphosphate synthase having greater thermostability than wild-type Sulfolobus acidocaldarius geranylgeranyl diphosphate synthase at 70 or 80 degrees Celsius, it does not support the mutant prenyl diphosphate synthase having greater thermostability than wild-type Sulfolobus acidocaldarius geranylgeranyl diphosphate synthase at any temperature.

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#### Conclusion

# [13] Status of the claims:

- Claims 1, 3-4, 6-7, 11-16, and 49-54 are pending.
- Claims 7 and 16 are rejected and claim 4 is objected to for reasons set forth above.
- Claims 1, 3-4, 6-7, 11-16, and 49-54 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/ Primary Examiner, Art Unit 1656